ASSEMBLY BILL No. 2156

Introduced by Assembly Member Niello

February 21, 2006

An act to amend Section 1241 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2156, as introduced, Niello. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services. Existing law exempts specified clinical laboratories and persons performing clinical laboratory tests from those requirements.

This bill would make a technical and nonsubstantive change to that provision.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1241 of the Business and Professions Code is amended to read:

1241. (a) This chapter applies to all clinical laboratories in California or *those* receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.

(2) Public health laboratories, as defined in Section 1206.

(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.

(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.

(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.

(6) Those that register with the State Department of Health Services pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes if the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:

(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of

the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.

(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.

(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.

(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.

(7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.

(8) Those certified emergency medical technicians and licensed paramedics providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Health Services in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any

registration or renewal fees nor shall they be subject to routine inspection by the State Department of Health Services.

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